

**K200968 ABC33L, ABC35L, ABC37L, ABC39L, ABC33R,  
ABC35R, ABC37R, ABC39R**Dec 28, 2020  
262 days to decisionK200968 · Product code: **CBI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k200968/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI) |
| Date received         | Apr 10, 2020  |
| Decision date         | Dec 28, 2020  |
| Days to decision      | 262 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Insung Medical Co., Ltd.</b>       |
| Location       | Gangwon-Do, KR                        |
| Contact        | Tae-il An                             |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

**REGULATORY CONSULTANT**

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|-----------------|------------------|
| Consulting firm | <b>KMC, Inc.</b> |
| Contact         | DongHa Lee       |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200968/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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